

Listing of the Claims

The following listing of claims replaces all previous claim lists.

1. (Withdrawn – currently amended) ~~A~~ An oral dosage form comprising ~~an a~~
water-insoluble activated adsorbent which exhibits a surface area greater than 100
m²/g when measured by the Brunauer-Emmett-Teller method using nitrogen as an
adsorptive material and an adverse agent, wherein at least a majority of the
adverse agent is adsorbed onto the adsorbent.
2. (Withdrawn – currently amended) The oral dosage form of claim 1, wherein
at least 80 wt.% of the adverse agent is adsorbed onto the adsorbent.
3. (Withdrawn – currently amended) The oral dosage form of claim 1, wherein
at least 90 wt.% of the adverse agent is adsorbed onto the adsorbent.
4. (Withdrawn – currently amended) The oral dosage form of claim 1, wherein
the adsorbent comprises at least one material selected from the group consisting of
activated charcoal, activated alumina, activated silicon dioxide, activated
bentonite, activated kaolin, and mixtures of any two or more of the foregoing.
5. (Withdrawn – currently amended) The oral dosage form of claim [4] 1,
wherein the adsorbent is activated charcoal.
6. (Withdrawn – currently amended) The oral dosage form of claim 1, further
comprising at least one hydrophobic material disposed at least on a portion of the
outer surface of the adsorbent.
7. (Withdrawn – currently amended) The oral dosage form of claim 6, wherein
the at least one hydrophobic material is selected from the group consisting of
acrylic and methacrylic acid polymers and copolymers, alkylcelluloses, natural
and synthetic waxes, water insoluble waxes, fatty alcohols, fatty acids,
hydrogenated fats, fatty acid esters, fatty acid glycerides, hydrocarbons, and

hydrophobic and hydrophilic polymers having hydrocarbon backbones, and mixtures of any two or more of the foregoing.

8. (Withdrawn – currently amended) The oral dosage form of claim 7, wherein the at least one hydrophobic material is selected from the group consisting of glycerol ~~monostearate~~-monostearate; beeswax; cetyl alcohol; stearyl alcohol; hydrogenated castor oil; hydrogenated cottonseed oil; ~~stearyl alcohol~~; stearyl acid; and mixtures of two or more of the foregoing.
9. (Canceled)
10. (Withdrawn – currently amended) The oral dosage form of claim 1, wherein the dosage form releases about 0.5 mg or less of the adverse agent *in vivo* following intact administration.
11. (Withdrawn – currently amended) The oral dosage form of claim 1, wherein the dosage form releases about 0.05 mg or less of the adverse agent following intact administration.
12. (Withdrawn – currently amended) A oral dosage form comprising:
a plurality of first particles comprising an active agent; and
a plurality of second particles comprising a water-insoluble activated adsorbent which exhibits a surface area greater than 100 m²/g when measured by the Brunauer-Emmett-Teller method using nitrogen as an adsorptive material and an adverse agent; wherein
at least a majority of the adverse agent is adsorbed onto the adsorbent.
13. (Withdrawn – currently amended) The oral dosage form of claim 12, wherein the adsorbent is selected from the group consisting of activated charcoal, activated alumina, activated bentonite, activated kaolin, and mixtures of any two or more of the foregoing.

14. (Withdrawn – currently amended) The oral dosage form of claim 13,
wherein the adsorbent is activated charcoal.
15. (Withdrawn – currently amended) The oral dosage form of claim 12,
wherein the plurality of second particles further comprise at least one hydrophobic
material disposed on at least a portion of the outer surface of the adsorbent.
16. (Withdrawn – currently amended) The oral dosage form of claim 15,
wherein the at least one hydrophobic material is selected from the group
consisting of acrylic and methacrylic acid polymers and copolymers,
alkylcelluloses, natural and synthetic waxes, water insoluble waxes, fatty alcohols,
fatty acids, hydrogenated fats, fatty acid esters, fatty acid glycerides,
hydrocarbons, and hydrophobic and hydrophilic polymers having hydrocarbon
backbones, and mixtures of any two or more of the foregoing
17. (Withdrawn - currently amended) The oral dosage form of claim 16, wherein the at
least one hydrophobic material is selected from the group consisting of glyceryl
~~monostearate~~ monostearate beeswax; cetyl alcohol; stearyl alcohol; hydrogenated
castor oil; hydrogenated cottonseed oil; ~~stearyl alcohol~~; stearic acid; and mixtures
of any two or more of the foregoing.
18. (Withdrawn – currently amended) The oral dosage form of claim 12,
wherein the active agent is an opioid agonist and the adverse agent is an opioid
antagonist.
19. (Withdrawn – currently amended) The oral dosage form of claim 18,
wherein the opioid agonist is selected from the group consisting of alfentanil,
allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide,
buprenorphine, butorphanol, clonitazene, codeine, desomorphine,
dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine,
dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl, butyrate,

dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacyl morphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metophon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, proheptazine, promedol, properidine, propiram, propoxyphene, sufentanil, tramadol, tilidine, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

20. (Withdrawn – currently amended) The oral dosage form of claim 19, wherein the opioid agonist is selected from the group consisting of morphine, codeine, hydromorphone, hydrocodone, oxycodone, oxymorphone, dihydrocodeine, dihydromorphine, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

21. (Withdrawn - currently amended) The oral dosage form of claim 18, wherein the opioid antagonist is selected from the group consisting of cyclazocine, naloxone, naltrexone, nalmeferne, nalbuphine, nalorphine, cyclazacine, levallorphan, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing, wherein the opioid antagonist selected is a different compound from the opioid agonist selected.

22. (Withdrawn – currently amended) The oral dosage form of claim 21, wherein the opioid antagonist is selected from the group consisting of nalmafene, naloxone, naltrexone, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

23. (Canceled)

24. (Withdrawn – currently amended) The oral dosage form of claim 23,
wherein the dosage form comprises a capsule containing the first particles and the
second particles.
25. (Withdrawn – currently amended) The oral dosage form of claim 12,
wherein the dosage form releases about 0.5 mg or less of the adverse agent *in vivo*
following intact administration.
26. (Withdrawn – currently amended) The oral dosage form of claim 25,
wherein the dosage form releases about 0.05 mg or less of the adverse agent *in*
vivo following intact administration.
27. (Withdrawn – currently amended) An oral dosage form comprising:
a plurality of first particles comprising an opioid agonist;
a plurality of second particles comprising an a water-insoluble
activated adsorbent which exhibits a surface area greater than 100
m²/g when measured by the Brunauer-Emmett-Teller method using
nitrogen as an adsorptive material and an an opioid antagonist;
wherein at least a majority of the opioid agonist is adsorbed onto the
adsorbent; and
wherein the first particles provide a controlled release of the opioid
agonist upon oral administration to a patient.
28. (Withdrawn) The oral dosage form of claim 27, wherein the first particles
and the second particles each have a size of from about 0.1 mm to about 3.0 mm
in any dimension.
29. (Withdrawn) The oral dosage form of claim 27, wherein the second particles
each comprise at least one hydrophobic material disposed on at least a portion of
the outer surface of the adsorbent.

30. (Withdrawn) The oral dosage form of claim 29, wherein the at least one hydrophobic material is selected from the group consisting of acrylic and methacrylic acid polymers and copolymers, alkylcelluloses, natural and synthetic waxes, water insoluble waxes, fatty alcohols, fatty acids, hydrogenated fats, fatty acid esters, fatty acid glycerides, hydrocarbons, and hydrophobic and hydrophilic polymers having hydrocarbon backbones, and mixtures of any two or more of the foregoing.

31. (Withdrawn – currently amended) The oral dosage form of claim 30, wherein the at least one hydrophobic material is selected from the group consisting of glyceryl ~~monostearate~~ monostearate beeswax; cetyl alcohol; stearyl alcohol; hydrogenated castor oil; hydrogenated cottonseed oil; ~~stearyl alcohol~~; stearic acid; and mixtures of any two or more of the foregoing.

32. (Withdrawn) The oral dosage form of claim 27, wherein the opioid agonist is selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl, butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacyl morphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metopon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, proheptazine, promedol, properidine,

propiram, propoxyphene, sufentanil, tramadol, tilidine, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

33. (Withdrawn) The oral dosage form of claim 32, wherein the opioid agonist is selected from the group consisting of morphine, codeine, hydromorphone, hydrocodone, oxycodone, oxymorphone, dihydrocodeine, dihydromorphone, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

34. (Withdrawn – currently amended) The oral dosage form of claim 27, wherein the opioid antagonist is selected from the group consisting of cyclazocine, naloxone, naltrexone, nalmeferene, nalbuphine, nalorphine, cyclazacine, levallorphan, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing, wherein the opioid antagonist selected is a different compound from the opioid agonist selected.

35. (Withdrawn) The oral dosage form of claim 34, wherein the opioid antagonist is selected from the group consisting of nalmafene, naloxone, naltrexone, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.

36. (Withdrawn) The oral dosage form of claim 27, wherein the dosage form comprises a tablet comprising the first particles and the second particles.

37. (Withdrawn) The oral dosage form of claim 27, wherein the dosage form comprises a capsule containing the first particles and the second particles.

38. (Withdrawn) The oral dosage form of claim 27, wherein the dosage form releases about 0.5 mg or less of the adverse agent *in vivo* following intact administration.

39. (Withdrawn) The oral dosage form of claim 38, wherein the dosage form releases about 0.05 mg or less of the adverse agent *in vivo* following intact administration.
40. (Currently amended) ~~A~~An oral dosage form comprising:
an active agent;
~~an a~~ a water-insoluble activated adsorbent which exhibits a surface area greater than 100 m²/g when measured by the Brunauer-Emmett-Teller method using nitrogen as an adsorptive material; and
an adverse agent; wherein at least a majority of the adverse agent is adsorbed onto the adsorbent.
41. (Currently amended) The oral dosage form of claim 40, further comprising at least one hydrophobic material disposed on at least a portion of the outer surface of the adverse agent adsorbed onto the adsorbent.
42. (Previously presented) The oral dosage form of claim 41, wherein the at least one hydrophobic material is selected from the group consisting of acrylic and methacrylic acid polymers and copolymers, alkylcelluloses, natural and synthetic waxes, water insoluble waxes, fatty alcohols, fatty acids, hydrogenated fats, fatty acid esters, fatty acid glycerides, hydrocarbons, and hydrophobic and hydrophilic polymers having hydrocarbon backbones, and mixtures of any two or more of the foregoing.
43. (Currently amended) The oral dosage form of claim 42, wherein the at least one hydrophobic material is selected from the group consisting of glyceryl ~~monostearate~~ monostearate beeswax; cetyl alcohol; stearyl alcohol; hydrogenated castor oil; hydrogenated cottonseed oil; ~~stearyl alcohol~~; stearic acid; and mixtures of any two or more of the foregoing.

44. (Currently amended) The oral dosage form 40, wherein the active agent is an opioid agonist and the adverse agent is an opioid antagonist.
45. (Currently amended) The oral dosage form of claim 44, wherein the opioid agonist is selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl, butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacyl morphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metophon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, proheptazine, promedol, properidine, propiram, propoxyphene, sufentanil, tramadol, tilidine, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.
46. (Currently amended) The oral dosage form of claim 45, wherein the opioid agonist is selected from the group consisting of morphine, codeine, hydromorphone, hydrocodone, oxycodone, oxymorphone, dihydrocodeine, dihydromorphine, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.
47. (Currently amended) The oral dosage form of claim 44, wherein the opioid antagonist is selected from the group consisting of cyclazocine, naloxone, naltrexone, nalmeferne, nalbuphine, nalorphine, cyclazacine, levallorphan,

pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing, wherein the opioid antagonist selected is a different compound from the opioid agonist selected.

48. (Currently amended) The oral dosage form of claim 47, wherein the opioid antagonist is selected from the group consisting of nalmafene, naloxone, naltrexone, pharmaceutically acceptable salts thereof, and mixtures of any two or more of the foregoing.
49. (Canceled).
50. (Currently ammended) The oral dosage form of claim 44, wherein the dosage form comprises a capsule containing a plurality of particles.
51. (Currently amended) The oral dosage form of claim 44, wherein the dosage form comprises a tablet.
52. (Currently amended) The oral dosage form of claim 40, wherein the activated adsorbent comprises at least one material selected from the group consisting of activated charcoal, activated alumina, activated bentonite, activated kaolin, and mixtures of any two or more of the foregoing.
53. (Currently amended) The oral dosage form of claim 40, wherein the adsorbent is activated charcoal.
54. (Currently amended) The oral dosage form of claim 40, wherein the dosage form releases about 0.5 mg or less of the adverse agent *in vivo* following intact oral administration.
55. (Currently amended) The oral dosage form of claim 54, wherein the dosage form releases about 0.05 mg or less of the adverse agent *in vivo* following intact oral administration.
56. (Currently amended). The oral dosage form of claim 40, wherein the dosage form further comprises:

a core comprising the activated adsorbent and the adverse agent; and
a shell comprising the active agent;
wherein the shell surrounds a majority of the core.

57. (Withdrawn) A method for preparing a dosage form comprising:
providing an adsorbent;
providing a liquid comprising an adverse agent;
contacting the adsorbent with the liquid comprising the adverse agent
for sufficient time to allow at least a portion of the adverse agent to
adsorb onto the adsorbent;
separating the adsorbent from the liquid phase; and
optionally, washing the adsorbent.
58. (Withdrawn) The method of claim 57, wherein the adsorbent comprises at
least one material selected from the group consisting of activated charcoal,
alumina, bentonite, kaolin, and mixtures of any two or more of the foregoing.
59. (Withdrawn) The method of claim 57, further comprising applying at least
one hydrophobic material to the outer surface of the adsorbent after removal of the
adsorbent from the liquid phase.
60. (Withdrawn) The method of claim 59, wherein the at least one hydrophobic
material is selected from the group consisting of acrylic and methacrylic acid
polymers and copolymers, alkylcelluloses, natural and synthetic waxes, water
insoluble waxes, fatty alcohols, fatty acids, hydrogenated fats, fatty acid esters,
fatty acid glycerides, hydrocarbons, and hydrophobic and hydrophilic polymers
having hydrocarbon backbones, and mixtures of any two or more of the foregoing.
61. (Withdrawn) The method of claim 57, wherein the adverse agent is an opioid
antagonist.

62. (Withdrawn) The method of claim 61, further comprising adding the adsorbent and an opioid agonist to a dosage form.
63. (Withdrawn) A method for preparing a dosage form comprising:
- providing an adsorbent;
 - providing a liquid comprising an adverse agent;
 - adding the adsorbent to a fluidized bed;
 - fluidizing the adsorbent;
 - spraying the liquid onto the fluidized adsorbent; and
 - optionally, drying the adsorbent.
64. (Withdrawn) The method of claim 63, wherein the adsorbent comprises at least one material selected from the group consisting of activated charcoal, alumina, bentonite, kaolin, and mixtures of any two or more of the foregoing.
65. (Withdrawn) The method of claim 63, further comprising applying at least one hydrophobic material to the outer surface of the adsorbent after removal of the adsorbent from the liquid phase.
66. (Withdrawn) The method of claim 65, wherein the at least one hydrophobic material is selected from the group consisting of acrylic and methacrylic acid polymers and copolymers, alkylcelluloses, natural and synthetic waxes, water insoluble waxes, fatty alcohols, fatty acids, hydrogenated fats, fatty acid esters, fatty acid glycerides, hydrocarbons, and hydrophobic and hydrophilic polymers having hydrocarbon backbones, and mixtures of any two or more of the foregoing.
67. (Withdrawn) The method of claim 63, wherein the adverse agent is an opioid antagonist.
68. (Withdrawn) The method of claim 63, further comprising adding the adsorbent and an opioid agonist to a dosage form.

69. (Withdrawn) A method of treating a condition, or a symptom thereof, in a patient comprising administering to the patient a dosage form according to claim 40.
70. (Withdrawn) A method of treating a patient for pain comprising administering to the patient a dosage form according to claim 27.
71. (Withdrawn) A kit for treating a patient for pain comprising a dosage form according to claim 27, and instructions for directing the administration of the dosage form to the patient for the treatment of pain.
72. (New) The oral dosage form of claim 40, wherein the activated adsorbent exhibits a surface area greater than 500 m²/g when measured by the Brunauer-Emmett-Teller method using nitrogen as an adsorptive material.
73. (New) The oral dosage form of claim 40, wherein the activated adsorbent exhibits a surface area greater than 1000 m²/g when measured by the Brunauer-Emmett-Teller method using nitrogen as an adsorptive material.
74. (New) The oral dosage form of claim 40, wherein the activated adsorbent further exhibits an adsorptive capacity as measured by adsorbance of methylene blue dye from aqueous solution of greater than 30 mg/g.
75. (New) The oral dosage form of claim 40, wherein the activated adsorbent exhibits an adsorptive capacity as measured by adsorbance of methylene blue dye from aqueous solution of greater than 150 mg/g.
76. (New) The oral dosage form of claim 40, wherein the activated adsorbent exhibits an adsorptive capacity as measured by adsorbance of methylene blue dye from aqueous solution of greater than 300 mg/g.
77. (New) The oral dosage form of claim 76, wherein the activated adsorbent is activated charcoal and the adsorbance of methylene blue dye is measured according to ASTM D3860-98.

78. (New) The oral dosage form of claim 76, wherein the activated adsorbent is activated clay and the adsorbance of methylene blue dye is measured according to ASTM C837-99.